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## IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

International Application No.

PCT/EP2003/011165

International Filing Date

October 9,2003

Priority Date(s) Claimed

October 10, 2002

Applicant(s) (DO/EO/US)

Hans-Georg KREYSCH

Title: BISPECIFIC ANTI-ERB-B ANTIBODIES AND THEIR USE IN TUMOR

**THERAPY** 

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

## Timing and Fees

$\boxtimes$		37 C.F.R. § 1.97(b), no fee or statement is required for filing this information sure statement is filed:
		within three months of the filing date of a national application other than a CPA under § 1.53(d);
		within three months of the actual filing date of the national phase of a PCT application; OR
	$\boxtimes$	before the mailing of a first substantive office action (including after filing of an RCE).
		37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods ied in 37 C.F.R. § 1.97(b), but before the mailing date of:
		a final rejection under 37 C.F.R. 1.113; termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR a notice of allowance under 37 C.F.R. § 1.311; and

		is acco	ompanied by:
			the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
			a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
			R. § 1.97(d), this information disclosure statement is filed after the mailing lowing actions which have not been withdrawn:
		a final	action under 37 C.F.R. § 1.113;
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		OR a r	notice of allowance under 37 C.F.R. § 1.311;
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			tement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of 00 under 37 C.F.R. § 1.17(p).
Staten	nents Ur	nder 37	C.F.R. 1.97(e)
			Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
			No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.
Cited	Materia	<u>ls</u>	
		ancest	s of materials listed but not attached were cited in benefit (35 U.S.C. § 120) for application Serial No, on Form 892 by the Examiner and/or Form by the applicant; see 37 C.F.R. § 1.98(d).
	$\boxtimes$	-	s of materials listed but not attached were cited in an international search dated February 18, 2005.
		Not re	equired by 37 CFR § 1.98.
		Copie	s of the materials listed are attached (except for the foregoing).

Non-Eng	glish Language References
	An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
[	A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
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The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

Anthony J. Zelano, Reg. No. 27,969

Attorney for Applicants

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Attorney Docket No.: MERCK-2989

Date: April 30, 2005

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Substitute	for form 1449A/PTO			Complete if Known		
				Application Number	Unassigned	
INFO	RMATION	DIS	CLOSURE	Filing Date	April 29, 2005	
STAT	<b>TEMENT BY</b>	Y AI	PPLICANT	First Named Inventor	Hans-Georg KREYSCH	
				Group Art Unit	Unassgiend	
	(use as many she	ets as	necessary)	Examiner Name	Unassigned	
Sheet	1	of	2	Attorney Docket Number	MERCK-2989	

U.S. PATENT DOCUMENTS								
Examiner Initials *	Cite No.1	U.S. Patent Document  Kind Code <sup>2</sup> Number ( <i>If known</i> )		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document			
	1	5587458			December 24, 1996			

		Foreign Patent Document		REIGN PATENT DOCUMI		Pages, Columns, Lines,		
Examiner Initials*	Cite No.1	Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	τ•
	2	wo	02055106		Merck Patent GmbH	July 18, 2002		
	. 3	wo	9400136		Molecular Oncology Inc.	January 6, 1994		Equv to cite 1
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INICOD	NA A TION	DICC		Application Number	Unassigned	
			LOSURE	Filing Date	April 29, 2005	
STATEMENT BY APPLICANT				First Named Inventor	Hans-Georg KREYSCH	
				Group Art Unit	Unassigend	
(us	se as many sh	eets as ne	ecessary)	Examiner Name	Unassigned	
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	4	YE D ET AL: "AUGMENTATION OF A HUMANIZED ANTI-HER2 MAB 4D5 INDUCED GROWTH INHIBITION BY A HUMAN-MOUSE CHIMERIC ANTI-EGF RECEPTOR MAB C225" ONCOGENE, BASINGSTOKE, HANTS, GB, VOL. 18, NO. 3, JANUARY 21, 1999 731-738, XP001096335	
	5	SCHMIDT M ET AL: "A BIVALENT SINGLE-CHAIN ANTIBODY-TOXIN SPECIFIC FOR ERB-2 AND THE EFG RECEPTOR" INTERNATIONAL JOURNAL OF CANCER, NEW YORK, NY, US, VOL. 65, NO. 4, FEBRUARY 8, 1996 PAGES 538-546, XP000646380	
	6	KASPRZYK P G ET AL: "THERAPY OF AN ANIMAL MODEL OF HUMAN GASTRIC CANCER USING A COMBINATION OF ANTI-ERBB-2 MONOCLONAL ANTIBODIES" CANCER RESEARCH, AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD, US, VOL. 52, 15 MAY 1992, PAGES 2771-2776, XP001093195	
	7	BASELGA J ET AL: "PHASE II STUDY OF WEEKLY INTRAVENOUS RECOMBINANT HUMANIZED ANTI-P185HER2 MONOCLONAL ANTIBDY IN PATIENTS WITH HER2/NEU-OVEREXPRESSING METASTATIC BREAST CANCER" JOURNAL OF CLINICAL ONCOLOGY, PHILADELPHIA, PA, US, VOL. 14, NO. 3, MARCH 1996 PAGES 737-744, XP000918166.	
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